

## **REMARKS**

### **1. Sections 1 and 2: Objections to the Drawings**

The objections to the drawings are addressed by the proposed drawing amendment discussed above, in accompaniment with the amendments to the specification. All claimed features are now clearly indicated. Note that claim 68 has been amended so that the parts (formerly "ends") are assigned reference numerals by the amendments to the specification.

### **2. Section 3: Abstract**

The abstract from the PCT Publication of the priority application (WO 00/07506) is added by the amendments.

### **3. Sections 4-9 of the Office Action: Rejection of Claims 51-66 under 35 USC §112(1)**

Kindly reconsider these rejections. It is submitted that the issue is not one of enablement, i.e., whether the specification describes the invention in such terms that one skilled in the art *can make and use* the claimed invention, since the specification contains such detail as per MPEP 2164. Rather, the rejections in issue would be more properly posed as objections under 37 CFR §1.75(d)(1) (lack of correspondence between claim terminology and specification), i.e., the issue is basically one of clarity. The specification and drawings have now been amended so that examples of the claimed features are more clearly indicated in the specification.

### **4. Sections 10-14 of the Office Action: Rejection of Claims 55 and 62 under 35 USC §112(1)**

The rejection of claim 55 should be obviated by the accompanying amendment. Regarding claim 62, the claimed structure is discussed (for example) at page 6 line 18 onward; however, to minimize difficulties in conforming the claims, drawing, and specification, the structure in issue has been removed from claim 62.

**5. Sections 15-18 of the Office Action: Rejection of Claims 68-69 under 35 USC §103(a) in view of U.S. Patent 6,190,401 to Green**

Reconsideration of the rejections is requested.<sup>1</sup> Initially, note that claim 68 recites elongated members (in the plural). If *Green* is regarded as having a pair of elongated members 302/303/308/304 (as shown in the Examiner's second drawing in the Office Action), *Green* neither discloses nor suggests bending each of the elongated members as recited in claim 68; rather, each elongated member stays straight, with the bioresorbable connection between them (see column 8 line 62 onward) being bent. Note that the Fig. 10 apparatus is shown "spread" merely because the bioresorbable connecting material is not rigid, and that the apparatus is not in fact bent when deployed: as depicted in Figs. 7-9 and described in the specification, the *Green* apparatus is driven forward in a U-shaped form, see Figs. 13 and 14, with each "arm" being in parallel and being driven by needle 302, see Figs. 13 and 15, and the apparatus remains in this configuration when deployed, without the spacing between the arms being varied. After deployment, the bioresorbable connection between the arms dissolves while the arms remain in tissue as retaining spikes (see, e.g., column 10 lines 55-60). Thus, *Green* has no teaching or suggestion that a fixator may include an elongated member (much less multiple elongated members) wherein each elongated member is bent from a linear form to a form wherein its ends are closely spaced, such that each elongated member retains a graft and artery together. *Green* is simply a rather conventional surgical staple having linear arms which remain in linear form when installed in tissue, but the "bridge" of the staple is made of dissolving (and flexible) material. Consider that this flexible material cannot maintain the arms in a closely spaced condition (and in fact it cannot hold the arms in any fixed location owing to its flexibility), and thus there is no way to use the *Green* apparatus to fix an artery and graft in the manner claimed, nor is there any apparent reason why one would be motivated to modify the *Green* apparatus to provide this capability. In

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<sup>1</sup> Note that the amendments to claim 68 to change "ends" to "parts" do not effect any substantive change to the scope of the claim, and rather are made to conform the language of claims 51 and 68 and ensure that all claimed features are denoted in the drawings.

contrast, look to Figs. 1 and 3 of the Applicant's drawings for illustration of the readily deployable, self-retaining aspects of an exemplary version of the claimed invention.

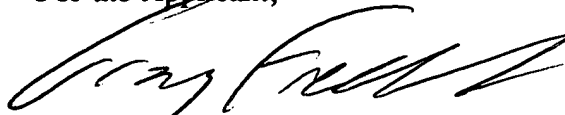
**6. Sections 19-21 of the Office Action: Allowance of Claim 70**

The indication that claim 70 is allowable is noted and appreciated. The claim is not rewritten in independent form because it is believed that the current independent claims are allowable for the reasons noted above.

**7. In Closing**

If any questions regarding the application arise, please contact the undersigned attorney. Telephone calls related to this application are welcomed and encouraged. The Commissioner is authorized to charge any fees or credit any overpayments relating to this application to deposit account number 18-2055.

For the Applicant,



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**ATTACHMENTS:**

- Amendment Sheet ("Marked-Up" Copy) Showing Changes to Application
- Submission of Proposed Drawing
- Amendment for Approval by Examiner
- New Abstract

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Serial No.: 09/762,223  
Filing Date: May 7, 2001  
Applicant(s): ANSON et al.  
Title:

Group Art Unit: 3731  
Examiner: Roberts, Paul A.  
Atty. Docket: 78104.018

**DEVICES AND METHODS FOR THE REPAIR OF ARTERIES**

**AMENDMENT SHEET ("MARKED-UP" COPY)  
SHOWING CHANGES TO APPLICATION  
(37 CFR §§1.121(b)(1)(iii); (c)(i)(ii))**

(To Accompany Response to September 25, 2002 Office Action)

In accordance with 37 CFR §§1.121(b)(iii) and (c)(ii), following are the amendments made to the specification and/or claims of the above-noted application.

- All deletions are indicated by brackets [like so] and all additions are indicated by underlining like so.
- The additions and deletions are made with respect to the application as it is understood to exist prior to entry of this amendment (i.e., any amendments are made with respect to the previous version).
- While 37 CFR §§1.121(b)(1)(iii) and (c)(1)(ii) does not require that new and canceled paragraphs and claims be supplied on this "marked-up" copy, such new additions and cancellations are nevertheless provided below to aid the reviewer's understanding.

**IN THE ABSTRACT:**

Please insert the Abstract provided on a separate sheet appended to this Response.

**IN THE SPECIFICATION:**

- Please delete the paragraph situated at page 12 lines 28-30 of the specification and insert the following replacement paragraph in its place:

Referring to the drawings, Fig. 1. illustrates a plan view of a wire-form fixator [2], connected by welding in the central area. The end termination of the fixator are sharpened and shown in the unconstrained (retaining) configuration. The fixator [2], which is shown in its retaining configuration, includes elongated members [300] each extending between first parts [302] and second parts [304], with the first parts [302] and second parts [304] being connected by resilient members [306].

- Please delete the paragraph situated at page 14 lines 21-24 of the specification and insert the following replacement paragraph in its place:

The stabiliser (Fig. 10) consists of two elastically deformable thin strips of metal (47) which, when unconstrained form a nominally circular shape (46). The two strips are riveted together (45) at the leading edge and are riveted onto a short metal tube (49) which has been arranged to retract within a catheter sheath (48). The metal tube (49) serves as a locating member for locating the device with respect to a catheter, and the distal portions of the strips (46) define support members (320) for supporting the catheter on the inner wall of an artery or graft. The proximal portions of the strips (46) then serve as resilient members (322) which connect the locating member (49) and the support members (320), with the resilient members (322) biasing the support members (320) toward the artery wall. As the resilient members (322) bias the support members (320) toward the artery wall, they reduce the distance between the end of each support member (322) and its resilient member (322), thereby causing the support member (322) to bow radially outward with respect to the locating member (49).

- Please delete the paragraph situated at page 16 lines 23-26 of the specification and insert the following replacement paragraph in its place:

Fig. 13 illustrates methods of forming the distal end of a dilator (110-112) and shows schematically, a single wire-form dilator element (107-109) and a wire-form deployment and envelope expansion mechanism in the form of a pulling wire (119) and a pushing/pulling tube (120). Each dilator element includes a dilating member (107) having a resilient member (350) connecting the dilating member (107) to a locating member (108) and biasing the dilating member (107) towards and into contact with the inner artery wall, whereby in use the resilient members (350) cause the dilating members (107) to apply outward pressure to the inner artery wall to dilate the artery. The pulling wire (119) serves as a means for reducing the distance between each dilating member (107) and each locating member (108), thereby causing the central section of said dilating member (107) to bow radially outward with respect to the locating member (108) in order to apply increased outward pressure on the inner wall of the artery when the device is in use.

**IN THE CLAIMS:**

Claims 55, 62, 68, and 69 are amended as follows:

55. **[AMENDED]** The fixator of claim 54 wherein **[both the first and the second parts are so sharpened] at least a portion of both the first and second parts is sharpened to enable said parts to pierce a graft and an artery.**
62. **[AMENDED]** The fixator of claim 51 included within a kit, the kit further comprising at least one of:
- a. a device for supporting a catheter within an artery or arterial graft, the device including:
    - (1) a locating member for locating the device with respect to the catheter,
    - (2) a plurality of support members for supporting the catheter on the inner wall of the artery or graft,
    - (3) a resilient member connecting the locating member and the support members, wherein the resilient member biases the support members towards the artery wall,
    - (4) means for reducing the distance between the end of each support member distal to the locating member and the end of said support member proximate the locating member, thereby causing the central section of said support member to bow radially outward with respect to the locating member;
  - b. a device for dilating an artery when delivered translumenally to a locus of an artery by means of a catheter, the device including:
    - (1) a locating member for locating the device with respect to the catheter;
    - (2) a plurality of dilating members,
    - (3) a resilient member connecting the dilating members to the locating member and biasing the dilating member towards and into contact with the inner artery wall, whereby in use the resilient members cause the dilating members to apply outward pressure to the inner artery wall and dilate the artery,
    - (4) means for reducing the distance between the end of each dilating member distal to the locating member and the end of said dilating member proximate the locating member, thereby causing the central section of said dilating member to bow radially outward with respect to the locating member in order to apply increased outward pressure on the inner wall of the artery when the device is in use[;
  - c. a device for retaining a graft on an artery, the device including an elongate member formed of a resilient material which biases said member into a helical configuration, at least one end of the member being sharpened to enable the member to pierce through the graft and the artery wall, wherein the member is moveable into an open configuration in which it can be conveyed along an artery].

68. **[AMENDED]** A fixator for retaining a graft on an artery, the fixator comprising elongated members:
- a. extending between first and second **[ends] parts**, and
  - b. being connected between their first and second **[ends] parts**,
- wherein each elongated member moves between:
- (1) an open configuration wherein the elongated member is at least substantially oriented along a linear axis with its first and second **[ends] parts** distantly spaced, and
  - (2) a retaining configuration wherein the elongated member is bent so that its first and second **[ends] parts** are closely spaced,
- whereby the elongated members of the fixator may in the open configuration be inserted into the circumference of a graft-bearing artery to pierce the graft and artery, and may then be moved to the retaining configuration to situate the graft and artery between the first and second parts.
69. **[AMENDED]** The fixator of claim 68 wherein at least one of the first and second **[ends] parts** of each of the elongated members is sharpened, whereby it may more easily pierce a graft and an artery.

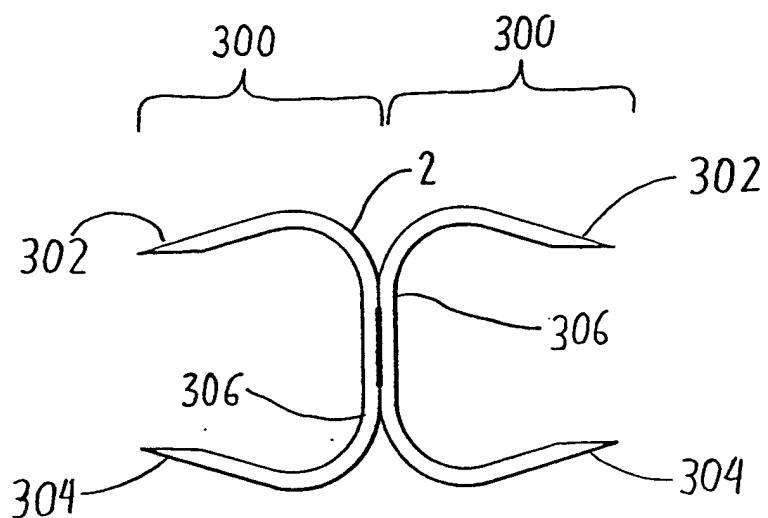


FIG. 1

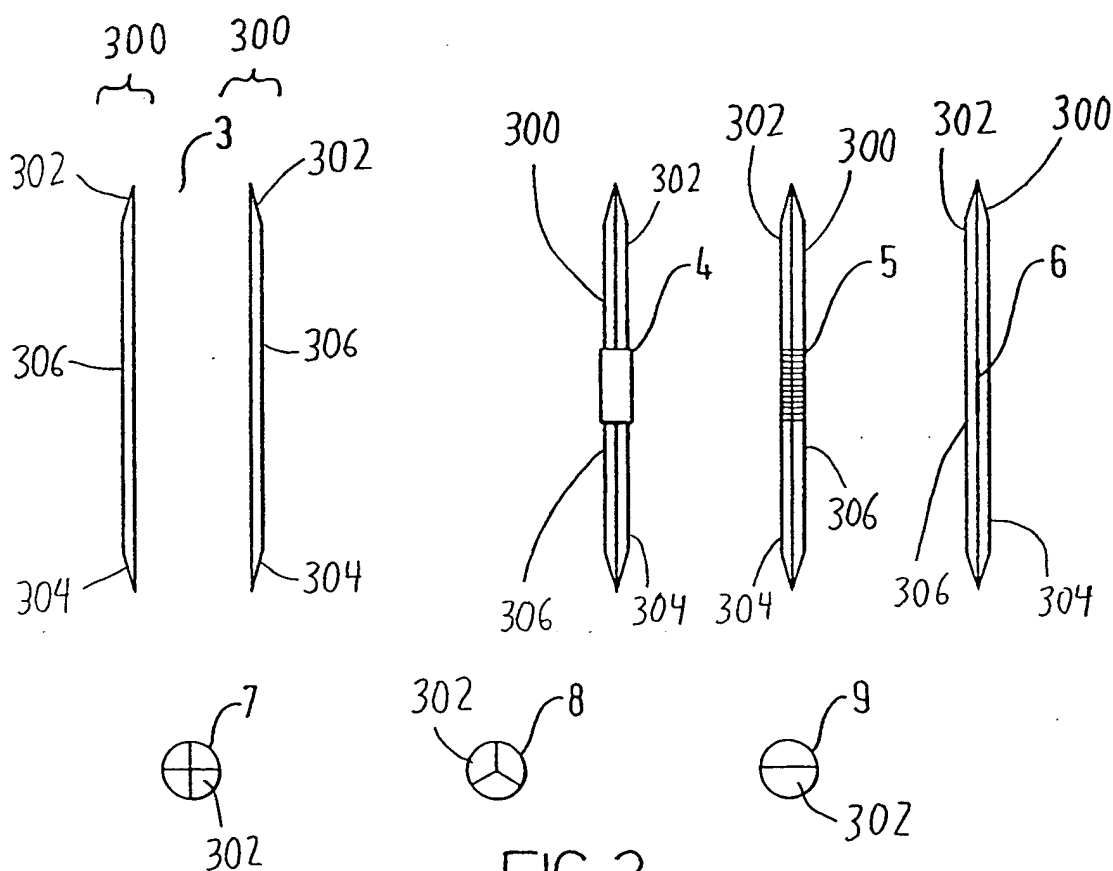


FIG. 2



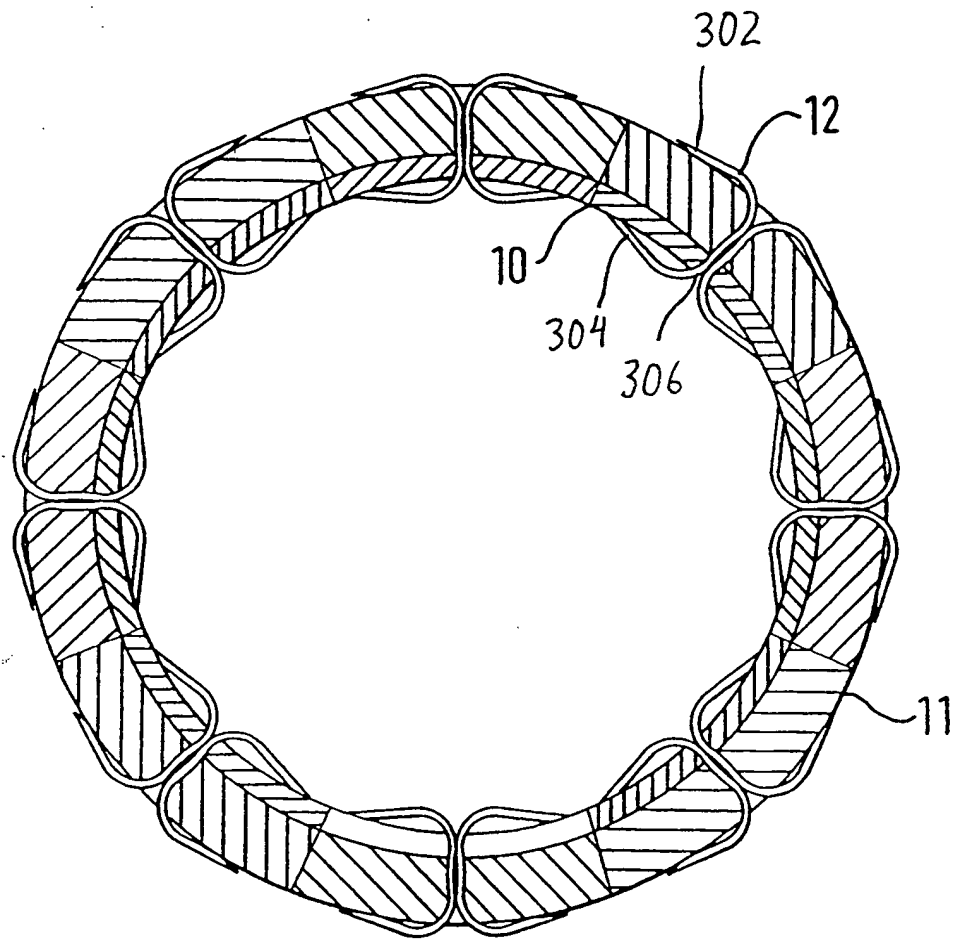


FIG. 3

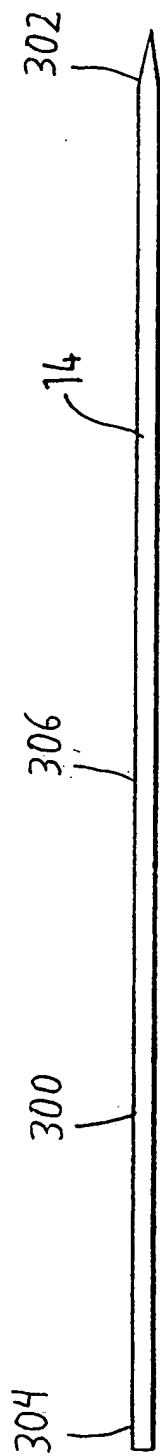
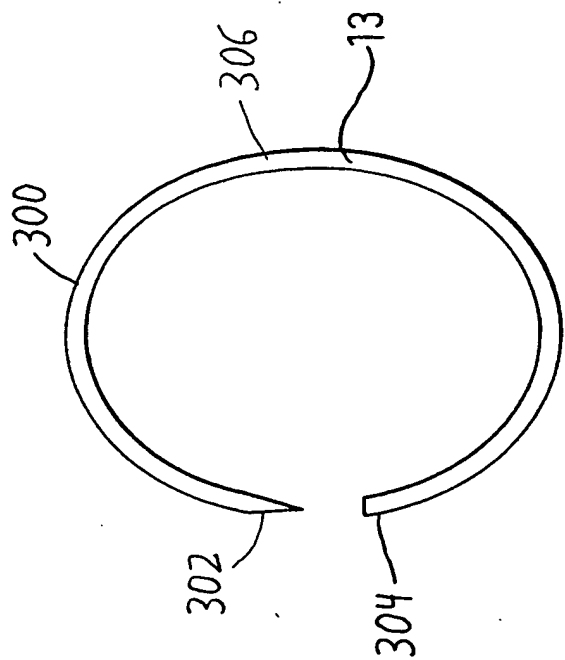


FIG. 4

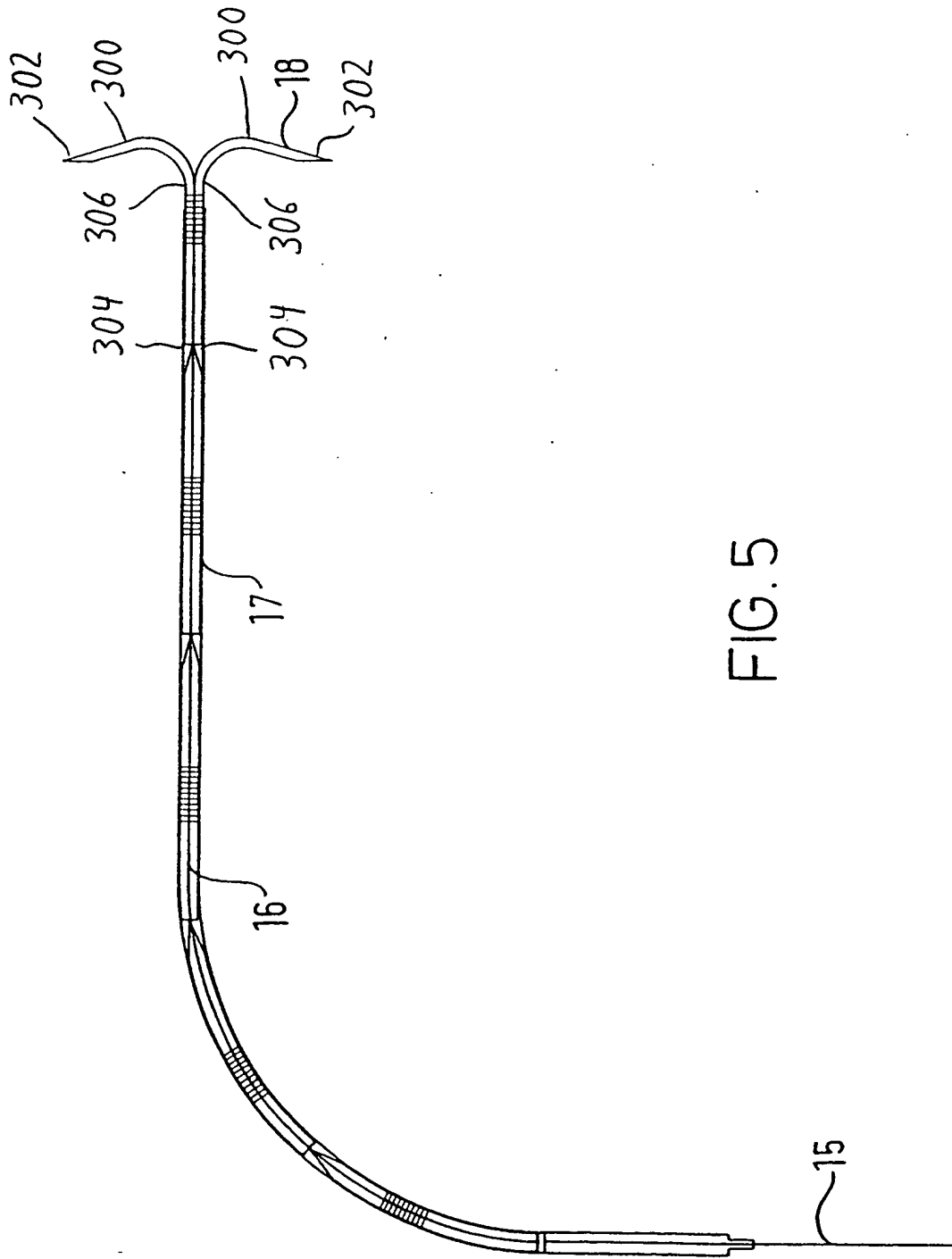


FIG. 5

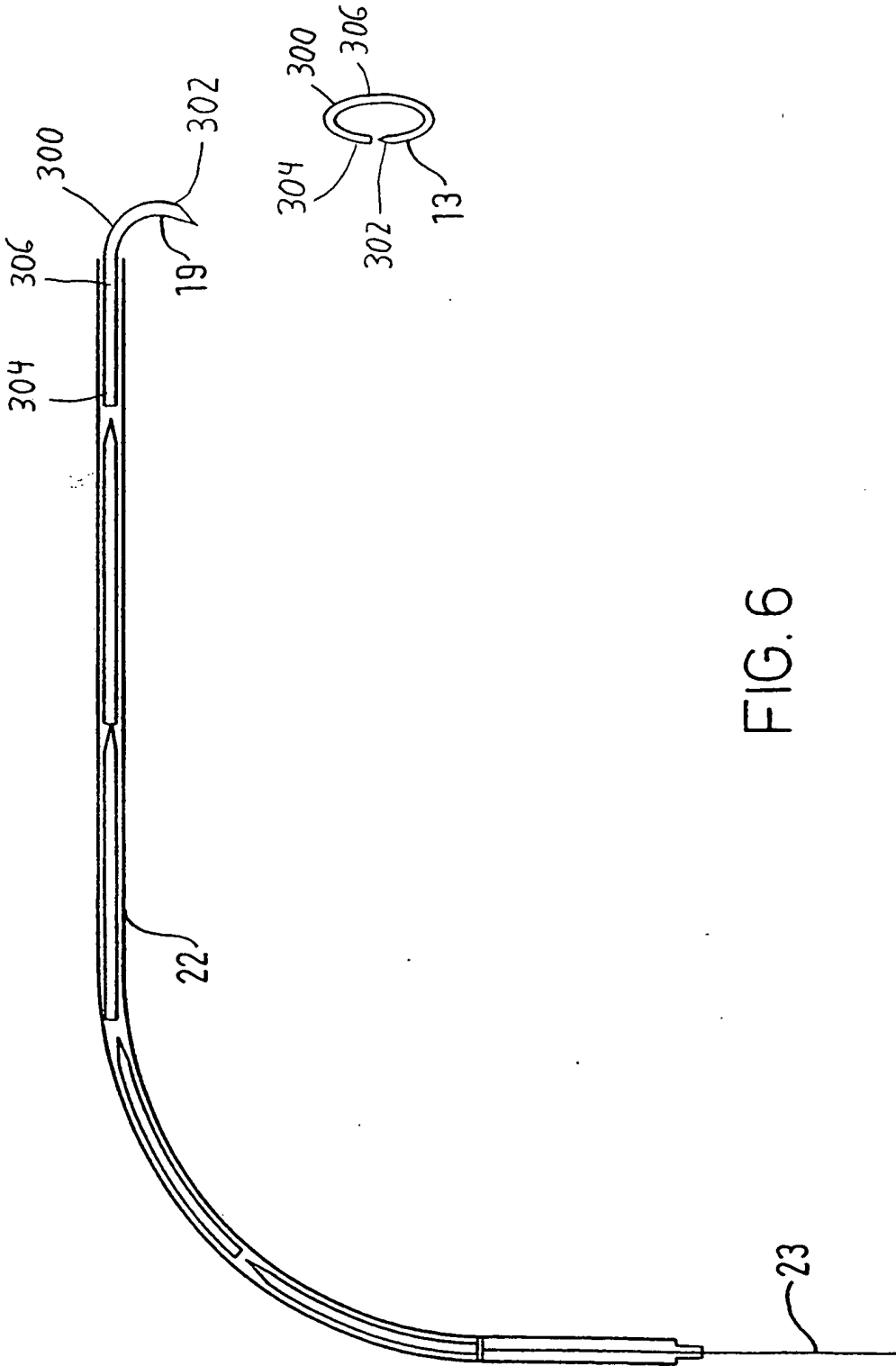


FIG. 6

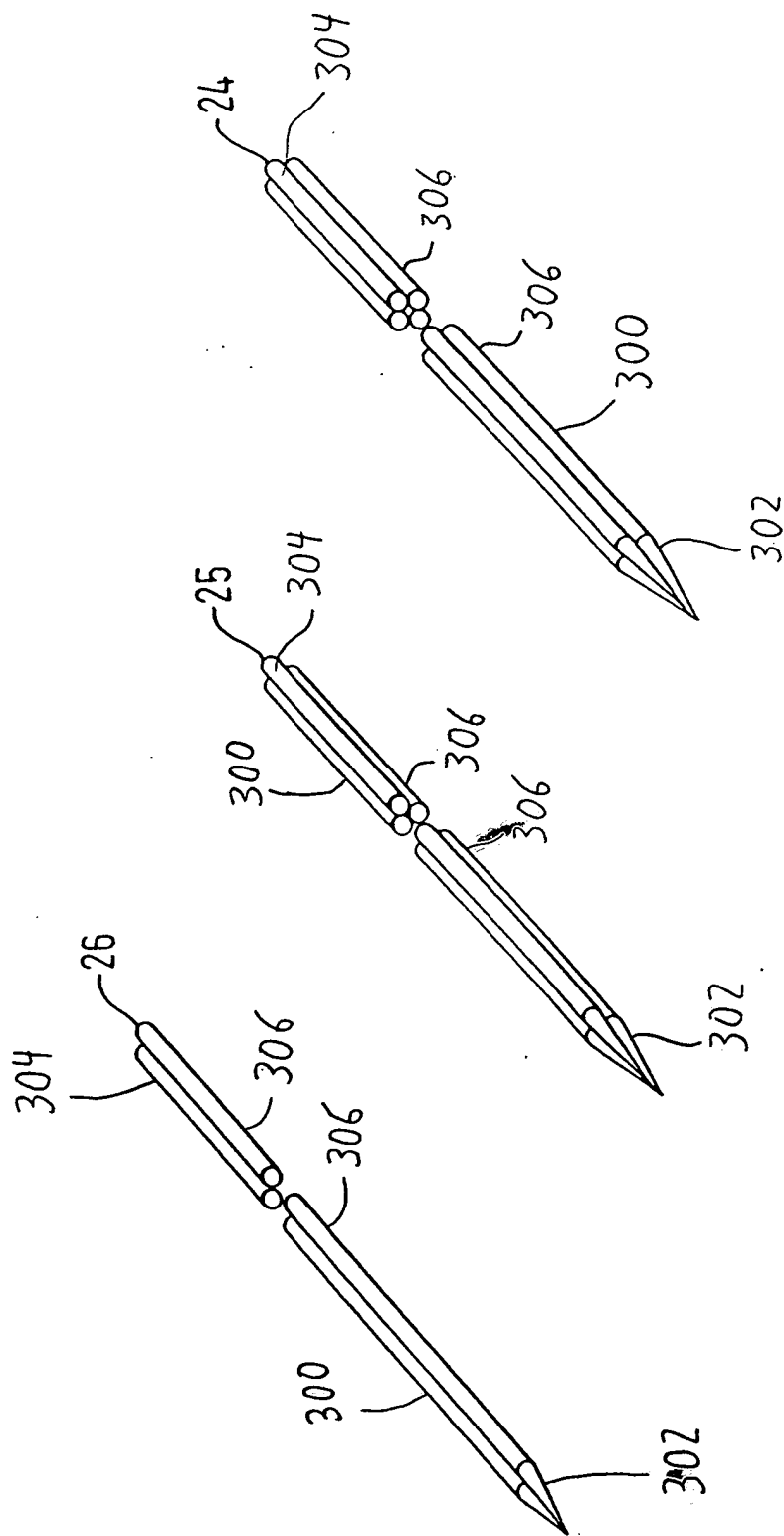


FIG. 7

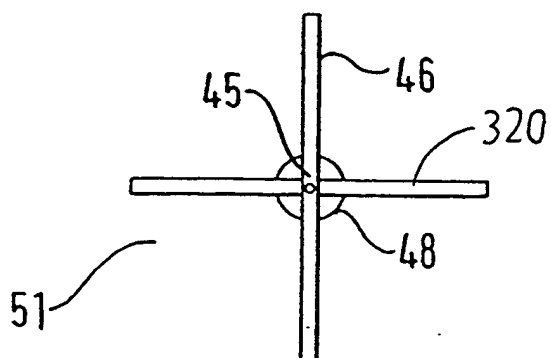
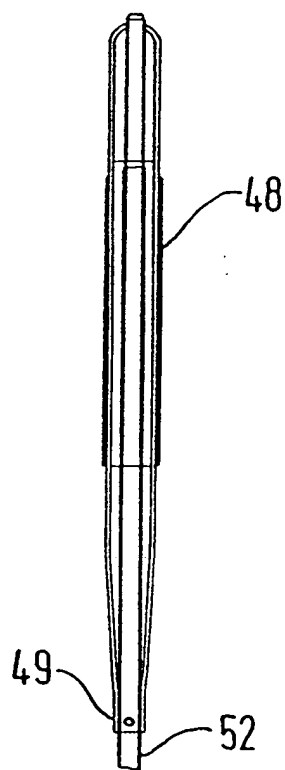
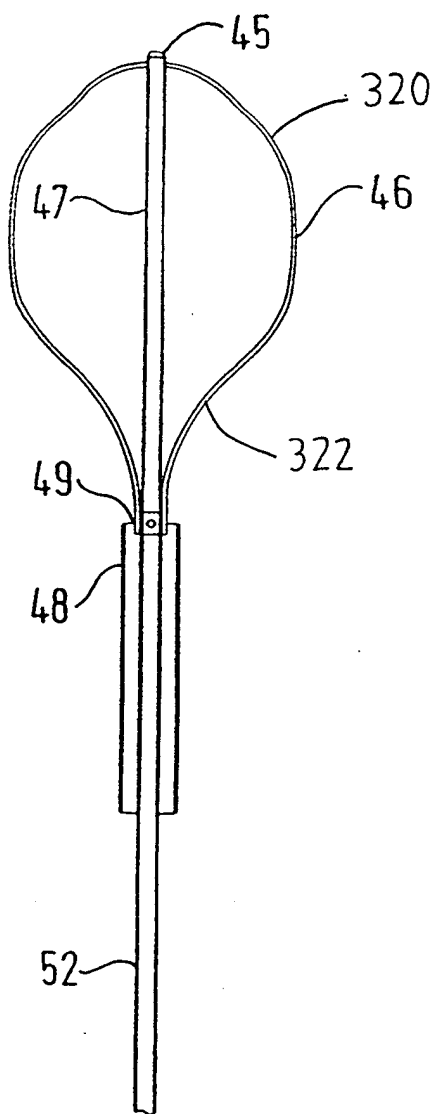


FIG. 10



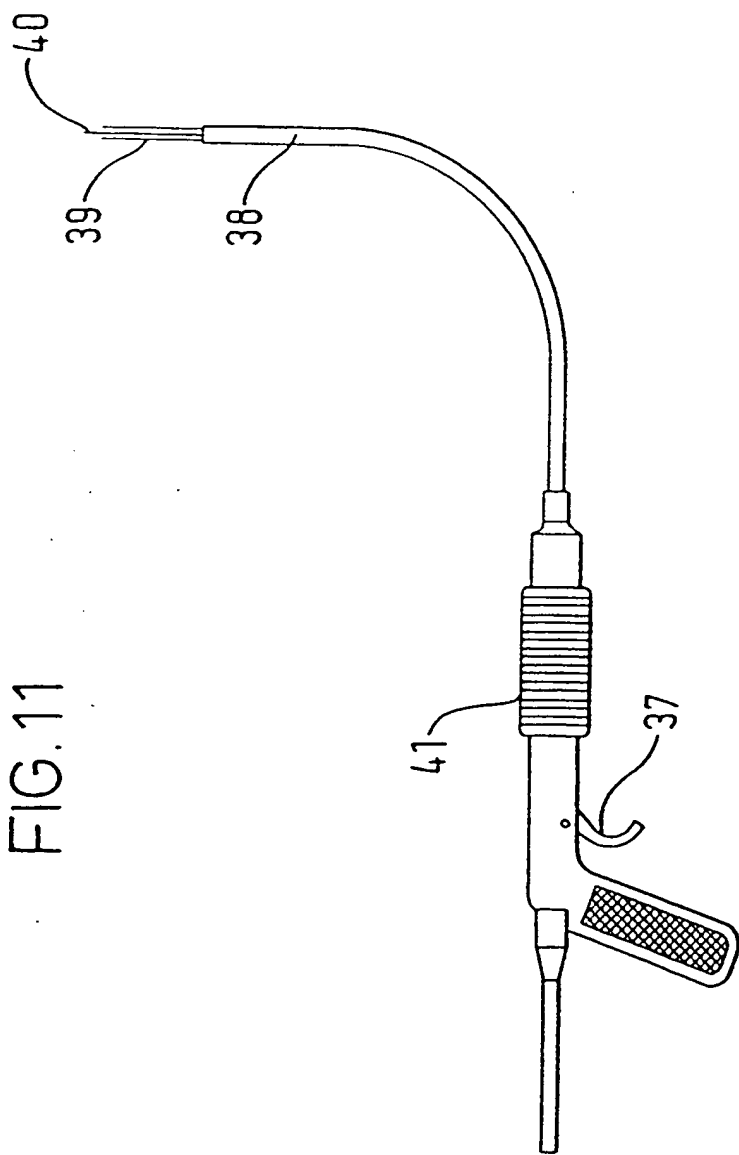
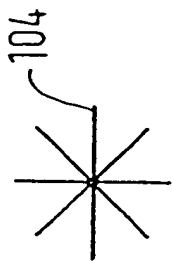


FIG. 11

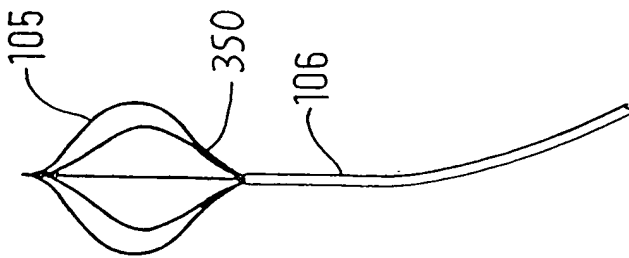


FIG. 12

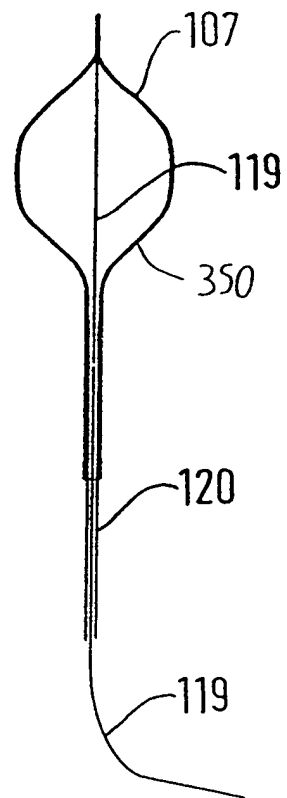
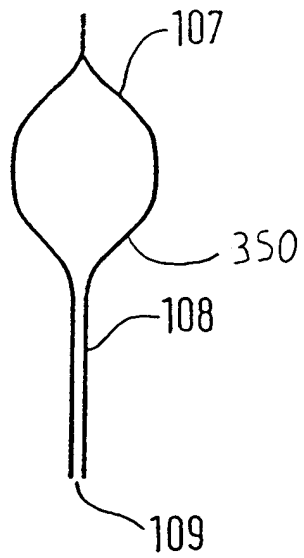
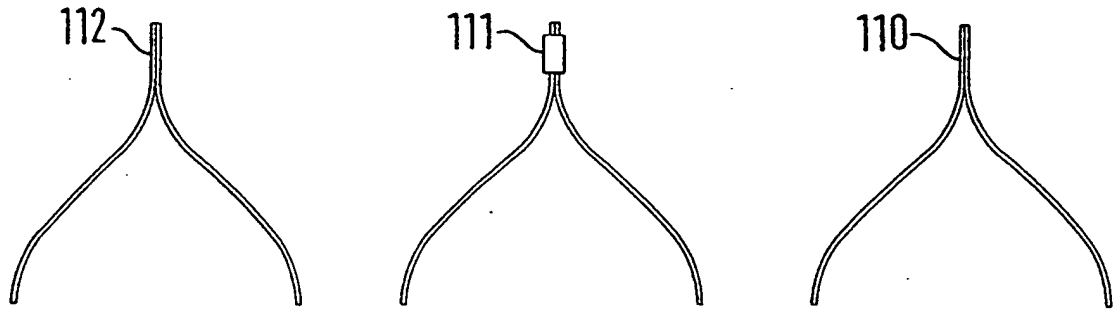


FIG. 13